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Honorable Claire C. Cecchi, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Bldg. & U.S. Courthouse
Courtroom MLK 5B
50 Walnut Street
Newark, NJ 07101

In Re: Proton-Pump Inhibitor Products Liability Litigation (No. II)
2:17-md-2789 (CCC)(MF) (MDL 2789)

Dear Judge Cecchi,

The Plaintiffs' Steering Committee (the "PSC") respectfully submits this letter in response to The Procter & Gamble defendants (collectively, "P&G") letter received yesterday afternoon giving the PSC an arbitrary take it or leave it deadline to agree to their terms of a 30(b)(6) deposition scheduled for next week or have it canceled. Exhibit A. By way of background, the 30(b)(6) pharmacovigilance deposition was first noticed by Plaintiffs in this MDL on October 3, 2017. The deposition is currently set for March 13, 2018, after being adjourned from February 6, 2018, due to disputes regarding the notice. While the parties were able to resolve several of our differences, there remains a key area of dispute that is preventing the deposition from moving forward. At issue is whether P&G's 30(b)(6) witness should be required to answer questions about the company's pharmacovigilance planning and practices for Prilosec OTC between May 1997 and the product launch in 2003.[1] The PSC would like the deposition to proceed as scheduled, which is why we respectfully request that the Court hear the disputed issues by telephone conference. Plaintiffs' counsel who has been negotiating this deposition notice with P&G, Paul Pennock, can be available this afternoon or Wednesday, if that is a convenient time for the Court. This letter explains the sequence of events giving rise to the dispute as it currently stands and explains the PSC's position on the appropriate scope of this deposition.

I. Timeline of Events

As the Court is aware, P&G is the seller of Prilosec OTC ("Over-the-Counter"). The AstraZeneca ("AZ") and Merck Defendants were the developers of the Prilosec prescription medication. In November 1997, P&G entered into an agreement with AZ to package, market, sell and distribute Prilosec OTC. On January 27, 2000, P&G filed an application with the FDA for

[1] The parties have agreed that the witness will be prepared to address pharmacovigilance during the time period from the product launch in 2003 to the present.

approval to do so. The FDA approved this application in June 2003, at which point P&G brought Prilosec OTC to market.

P&G was first named as a party defendant on October 14, 2016, ten months before this MDL was created. On May 1, 2017, Plaintiffs served P&G, as well as other defendants, with eight 30(b)(6) deposition notices, including one covering pharmacovigilance that contained 39 topics for examination (the "SDIL Notice"). The Honorable David R. Herndon, United States District Judge in the District Court for the Southern District of Illinois, ordered all defendants before him, including P&G, to complete all initial 30(b)(6) depositions by June 7, 2017. At that time, P&G had raised no objections to the 30(b)(6) notices, including pharmacovigilance. An agreement was later reached to not conduct the depositions until the MDL petition was decided. Thus, by the time this MDL was formed, P&G had known for several months the nature of the 30(b)(6) deposition notice on the topic of pharmacovigilance.

As mentioned, in this MDL, the PSC served P&G with a 30(b)(6) deposition notice that covered the topic of pharmacovigilance (the "October Notice") on October 3, 2017. Exhibit B. Notably, however, the October Notice contained only 17 topics - 22 fewer topics than the SDIL Notice with which P&G had previously taken no issue. By any measure, P&G reasonably should have expected to receive the notice in the MDL, and, furthermore, should have already been preparing a witness to testify on these matters from 1989 to the present. However, an additional period of meet and confer took place.

In January, the parties had at least agreed that the deposition would take place on February 6, 2018. However, on January 25, only 12 days before the deposition was scheduled to occur, counsel for P&G emailed the PSC a letter that purportedly responded to an email from Tracy Finken, PSC Executive Committee member, sent nearly *two months earlier* on December 9, 2017. P&G's counsel advised the PSC that the witness being produced, Michael Steinbuch, would "be prepared to address questions concerning the . . . topics as they are generally relevant and as they relate to P&G and Prilosec OTC from 2009 to the present." Importantly, the topics of the deposition had also been drastically altered, and the number of topics reduced from 17 to only six. A meet and confer ensued and it came to light that P&G had unilaterally misinterpreted the December 9th email and come to the preposterous conclusion that the December 9th email from Ms. Finken gave P&G *carte blanche* to totally disregard the topics and timeframes set forth in any of the 30(b)(6) notices. Apparently, P&G thought they could prepare and produce a witness on topics and timeframes as P&G saw fit and if Plaintiffs had any issues with the unilaterally decided upon limitations, the PSC would take those up with the Court after the deposition was complete.

The PSC responded to Mr. Green's letter on January 29, 2018, indicating our refusal to agree to a notice with such unacceptable and illogical limitations and reiterated the desire to obtain testimony on pharmacovigilance at least from the time Prilosec OTC was approved for marketing and sales until the present. Furthermore, if obtaining testimony that covered this time period required more than one witness, we advised that Plaintiffs must depose the witness covering the earliest time period first. As a result, the February 6th deposition was cancelled by agreement on January 30th, and the parties eventually agreed that the deposition would go forward on March 13, 2018. Subsequently, we were advised that the witness who would testify on the matters for examination for the time period from 2003 – 2009 would be, surprisingly, Michael Steinbuch--the same witness P&G intended to produce on February 6th.

On February 5th, P&G finally produced its objections and responses to Plaintiffs' First Set of Interrogatories. While P&G's responses were deficient, the responses did contain certain information Plaintiffs were unaware of, including that P&G first entered into its licensing agreement with AZ to market Prilosec OTC on November 20, 1997. In light of this information, the PSC revised its deposition notice to include coverage extending back to May 20, 1997, thereby encompassing any discussions had, communications exchanged, or documents created pertaining to pharmacovigilance that may have occurred during the agreement's negotiations.

Plaintiffs sent that revised deposition notice (the "February Notice") to P&G on February 16th. Exhibit C. Reflecting good faith dealings, Plaintiffs' February Notice included *verbatim* each of the topics P&G proposed in Mr. Green's January 25 letter. The February Notice also included five additional topics from the October Notice that the PSC deemed too critical to delete, but the additional topics were amended in accordance with other similar changes by P&G to make their inclusion agreeable to P&G.[2]

Presently, P&G refuses to produce a witness or educate one to cover topics for the period of time extending back to May 1997. Additionally, P&G claims that two of the topics in the February Notice are inappropriate for their designated pharmacovigilance witness to testify about. As a result, P&G refuses to agree with the notice, thereby *again* holding up the parties from moving forward with the deposition on March 13, 2018. The topics P&G refuses to agree to are:

- "Any evaluations, analysis, discussions, recommendations, or reports pertaining to premarketing risk and/or safety assessments, or risk reduction relating to Prilosec OTC and/or other PPI Product(s)."
- "Any protocols, evaluations, analysis, discussions, recommendations, reports, or guidance documents relating to the identification, collection, evaluation, analysis, and reporting of adverse events that occurred during any clinical testing of Prilosec OTC and/or other PPI Product(s)."

II. The Scope of the Pharmacovigilance Deposition

1. P&G must produce a witness (or, if needed, multiple witnesses) who can testify about agreed upon topics as they concern the period from May 20, 1997, until present.

One day before the deposition was originally scheduled to take place, P&G produced its responses to Plaintiffs' First Set of Interrogatories, which stated in response to Plaintiffs' interrogatory #2 that "Defendant entered into a License Agreement with AstraZeneca LP ('AZ') on November 20, 1997 to market Prilosec OTC." P&G also produced the actual agreements on February 20th. P&G's recent interrogatory responses and the licensing agreements themselves informed Plaintiffs about new lines of inquiry regarding the roles played at various times by different defendants involved with Prilosec OTC that are critically important to explore during the 30(b)(6) deposition on pharmacovigilance.

Proper pharmacovigilance depends on a defined and organized process and personnel structure that is faithfully followed. Indeed, under 21 CFR 314.80(b), the marketer of a drug is required to obtain adverse events information from a variety of sources including but not limited to clinical trials, post-marketing experience, and published scientific literature relating to the drug.

[2] For example, discussions about decisions, procedures and documents resulting from P&G's Prilosec OTC premarketing safety and/or risk assessments, and processes, analyses, documents, or decisions related to adverse event related activities during clinical testing.

Further, the marketing company is required to develop written procedures and policies for identifying and reporting such events to the FDA. *Id.* While P&G contends it had no pharmacovigilance responsibilities prior to the product launch, this position is at odds with both the law and practice. Clearly, long before Prilosec OTC was brought to market in 2003, P&G was obligated to plan for and create a pharmacovigilance process and structure to deal with adverse event reports that may be sent to them or published in the medical literature.

Further, to the extent P&G learned of adverse events during the development phase - whether from clinical trials or medical literature - P&G was obligated to report them to the FDA while the NDA for Prilosec OTC was pending approval. Exploring the details of P&G's creation and implementation of this process in the time period prior to launch is necessary to explore deficiencies that may have existed. In this case, it is striking that with such massive use of this medication that the incidence of acute kidney injury did not quickly become apparent to P&G through a proper pharmacovigilance process. Plaintiffs believe and have alleged that P&G's pharmacovigilance completely failed to detect the kidney risks with Prilosec OTC and this is part of the basis for their liability in this matter. Thus, Plaintiffs need to learn what P&G did or failed to do with respect to pharmacovigilance from the company's first involvement with this medication.

2. A P&G pharmacovigilance witness must testify about these noticed topics: (1) discussions about, decisions procedures, and documents resulting from P&G's Prilosec OTC premarketing safety and/or risk assessments; and (2) processes, analyses, documents, or decisions related to adverse event related activities during clinical testing.

P&G refuses to produce a witness who can testify as to certain pharmacovigilance topics in the February Notice. P&G claims certain topics are inappropriate for a pharmacovigilance witness, and others were duplicative, having clearly misunderstood what the topics were meant to encompass.

P&G's refusal to produce a witness who can testify as to these matters ignores how critical it is to learn about P&G's pharmacovigilance related activities during this time, which P&G's counsel claims there was none. For example, if P&G's counsel is correct, Plaintiffs expect to learn the extent to which P&G conducted little or no pharmacovigilance duties while developing Prilosec OTC with AZ, such as during the clinical trials that preceded market launch. Furthermore, Plaintiffs expect to learn that, for example, the P&G group responsible for premarketing safety and/or risk analysis did not even attempt to obtain, read, or consider significant peer-reviewed articles and studies on omeprazole (and even some of AZ's) which indicated histopathological kidney changes and renal toxicity. Under 21 CFR 314.80(b), AZ was required to regularly monitor this information. Thus, after entering the agreement with AZ and beginning to co-develop Prilosec OTC, P&G should have requested, obtained and reviewed all nine years of information AZ would have acquired since Prilosec was approved, including medical literature and adverse event and/or other safety/risk information.

Plaintiffs' recent review of the licensing agreement and other late, recent productions proves the necessity of exploring what safety and risk-related activities P&G took while developing Prilosec OTC, how those duties were allocated and how the information learned during such activities (if any) informed P&G's postmarketing approach to pharmacovigilance. As Your Honor knows, Plaintiffs' allege P&G's pharmacovigilance was deficient and caused P&G to not detect the safety signal on various kidney injuries as early as they should have. Furthermore,

Plaintiffs need to inquire whether, and, if so, which P&G group was responsible for premarketing safety and/or risk analysis.

P&G undeniably had a duty to conduct proper pharmacovigilance for Prilosec OTC. If P&G outsourced that to a third party, including AZ, that does not discharge that duty vis-a-vis the Plaintiffs. It is Plaintiffs' position that regardless of contractual agreements between P&G and third parties on pharmacovigilance, P&G was, at all relevant times that it was selling this drug, responsible for ensuring that pharmacovigilance was being properly conducted and properly acted upon. Accordingly, we are entitled to fully explore with P&G the nature of the pharmacovigilance as to these drugs without exception based on what they outsourced.

III. Conclusion

In conclusion, to avoid further delay and make this deposition as fruitful as possible, Plaintiffs request that the Court order P&G to produce a witness who can testify about the topics in Plaintiffs' February Notice from 1997 until the present.

Dated: March 6, 2018

Respectfully submitted,

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